MAY - 1 2000

Appendix E

510(K) SUMMARY
A100 AESTHETIC DIODE LASER SYSTEM

K000982

This 510(k) summary of safety and effectiveness for the diode laser system is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.


Applicant: Diomed, Inc.

Address: 23 Main Street
Andover, MA 01810

Contact Person: David Vivian
General Manager

Telephone: 978-475-7771
978-475-8488 (fax)


Preparation Date: March, 2000
(of the Summary)

Device Name: A100 Aesthetic Diode Laser

Common Name: Surgical Laser: GaAlAs Semiconductor Diode Laser

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (see: 21 CFR 878.4810). Product Code: GEX. Panel: 79.

Legally marketed predicate device: LaserLite Diode Laser System (K980142 and K981090) and the Diomed 15W Surgical Diode Laser (K962354)

Description of the Device: The A100 Aesthetic Diode Laser is a semiconductor diode laser operating at 810 $\pm$ 20 microns.

Indications for Use:

The A100 Aesthetic Diode Laser is indicated for:

- Incision, excision, vaporization, ablation, cutting, hemostasis, and coagulation of soft tissue in dermatology and plastic surgery, including aesthetic surgery; and
- treatment of pigmented and vascular lesions including leg veins.

Comparison to: The specifications of the A100 Aesthetic Diode Laser are the same or very similar to those of the claimed predicates.

Performance Data: None. The specifications and indications for use of the A100 Aesthetic Diode Laser System are the same or very similar to those of the claimed predicate devices. The A100 Aesthetic Diode Laser has the same indications for use for which the claimed predicates have been cleared and has no additional indications for use.

Because of this, performance data were not required.

Conclusion: Based on the foregoing, Diomed believes that the A100 Aesthetic Diode Laser is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2000

Diomed, Inc.
c/o Ms. Maureen O'Connell
1 Wing Road
Lynnfield, Massachusetts 01940

Re: K000982
Trade Name: A100 Aesthetic Diode Laser
Regulatory Class: II
Product Code: GEX
Dated: March 24, 2000
Received: March 27, 2000

Dear Ms. O'Connell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K000982

Device Name: A100 Aesthetic Diode Laser

Indications For Use:

The A100 Aesthetic Diode Laser is indicated for:

- Incision, excision, vaporization, ablation, cutting, hemostasis, and coagulation of soft tissue in dermatology and plastic surgery, including aesthetic surgery; and
- treatment of pigmented and vascular lesions including leg veins.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use X
(Per 21 CFR 810.109)

Over-The-Counter Use ____

Donna R. Lochner.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000982